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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,185	01/28/2004	Heejeong Yoon	REX 7034	3770
7590	08/23/2006		EXAMINER	
The Law Offices of Valerie E. Looper 11726 Lightfall Court Columbia, MD 21044			MCGARRY, SEAN	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 08/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/766,185

Applicant(s)

YOON ET AL.

Examiner

Sean R. McGarry

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/28/04</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "a compound, RX-0047, having a sequence comprising Seq. Id. No. 2". This recitation is unclear since the specification states, for example, "[T]he oligomers comprising either 5 or 10 nucleotides upstream and downstream from the sequence where the 20-mer of RX-0047 and RX-0049 were derived" (see page 10, for example). The specification indicates that both RX-0047 and RX-0049 are 20mers of a defined sequence (see Tables 1 and 2, for example). It is unclear, in the context of the instant claim, how RX-0047 could have a sequence *comprising* SEQ ID NO: 2 when the specification indicates that RX-0047 is SEQ ID NO: 2.

Claim 1 recites at line 3 "wherein said oligonucleotide compound". There is insufficient antecedent basis for this recitation.

Claims 2-5 are rejected in so far as they depend from claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thru et al [US 2004/0096848].

The claimed invention is drawn to an oligonucleotide, RX-0049, SEQ ID NO: 4 and where the oligonucleotide inhibits the expression of human HIF-1. The invention includes that the oligonucleotide be an antisense oligonucleotide and further wherein the oligonucleotide has phosphorothioate linkage and to a methods of inhibiting HIF-1 in cells or tissues where such methods include inducing cytotoxicity in a cancer cell.

Thru et al teach the inhibition of HIF-1 alpha via antisense oligonucleotides (see claims 1-36, for example). Thru et al have taught phosphorothioate linkages in the antisense oligonucleotides (see claim 8, for example). Thru et al have taught the

inhibition of HIF-1 alpha in the treatment of cancer where the method includes inducing cytotoxicity (see claims 24-36, for example).

The only different between Thru et al and the instant invention is that Thru et al do not specifically disclose SEQ ID NO: 4.

However, claims 1 and 2 of Thru et al claim HIF-1 alpha antisense oligonucleotides that are 8-50 nucleobases in length that comprise at least an 8 nucleobase portion of recited SEQ IDs. Included within those SEQ IDs is SEQ ID NO: 13. SEQ ID NO: 13 is a 16mer that aligns within the instant SEQ ID NO: 4. SEQ ID NO: 13 aligns with residues 4-19 of the instant SEQ ID NO: 4. At paragraph [0074] it is taught that particularly preferred compounds are antisense oligonucleotides comprising from about 12 to 30 nucleobases and most preferably are antisense compounds comprising about 12-20 nucleobases. With the above teachings it is clear that the instantly claimed SEQ ID NO: 4 is an obvious variant of the claimed invention of Thru et al. One of ordinary skill in the art would clearly recognize that SEQ ID NO: 4 is within the scope of the claimed invention of Thru et al and furthermore is within the defined preferred embodiments of the invention of Thru et al.

The invention as a whole would therefore have been *prima facie* obvious to one in the art at the time the invention was made.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ward et al [US 2004/0220393] discloses antisense oligonucleotides targeted to HIF-1. Ward et al disclose SEQ ID NO: 187 which is an

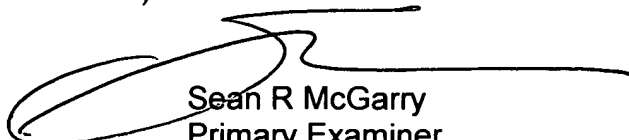
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18mer that aligns with residues 3-20 of the instant SEQ ID NO: 2. However, support for SEQ ID NO: 187 in the priority document of 2004/0220393 could not be found and is therefor not considered prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R. McGarry whose telephone number is (571) 272-0761. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Sean R McGarry
Primary Examiner
Art Unit 1635